In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS

DAVID BORDEN, as Personal Representative of the Estate of Mona Borden,	*	No. 19-1526V
Petitioner,	*	Special Master Christian J. Moran
v.	*	Filed: October 6, 2022
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	Severity; residual effect; bone marrow biopsy; bone marrow aspiration; surgical intervention; thrombocytopenic purpura; influenza ("flu") vaccine.
Respondent.	*	

Mark T. Sadaka, Law Offices of Sadaka Associates, LLC, Englewood, NJ, for Petitioner;
Julia M. Collison, United States Dep't of Justice, Washington, DC, for Respondent.

PUBLISHED DECISION DENYING ENTITLEMENT[1]

Ms. Borden alleged that the influenza ("flu") vaccine she received on October 3, 2016 caused her to suffer from thrombocytopenic purpura. Pet., filed Oct. 2, 2019. However, for the reasons explained below, petitioner has not

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. This posting will make the decision available to anyone with the internet. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

demonstrated that Ms. Borden's injury satisfies the Vaccine Act's ("the Act") severity requirement. Accordingly, petitioner is not entitled to compensation.

I. Procedural History

Ms. Borden filed her petition on October 2, 2019. The petition alleges Ms. Borden received a flu vaccine on October 3, 2016 and that, shortly thereafter, she began to suffer from thrombocytopenic purpura. Pet. at 1. She claimed the condition was either caused-in-fact by the vaccination or significantly aggravated by the vaccine. Id.

Ms. Borden filed medical records on October 14, 2019 and February 11, 2020. She filed an affidavit on April 13, 2020, clarifying her position. Additional medical records were filed on May 20, 2020 and December 15, 2020.

Anticipating the potential for the parties to retain experts, the undersigned issued draft expert instructions on December 22, 2020. However, the parties ultimately did not file any expert reports.

The Secretary filed his Rule 4 Report on January 6, 2021, contesting entitlement.[2] The Secretary identified several problems with Ms. Borden's case. Ms. Borden had not filed an expert report supporting her claim, and the onset of her symptoms was outside the Table's range for which a presumption of causation would be appropriate for thrombocytopenic purpura after an MMR vaccine. Resp't's Rep., filed Jan. 6, 2021, at 10. Another major issue, the Secretary argued, was that Ms. Borden's clinical course did not satisfy the Act's severity requirement. Id. This issue ultimately defined this case.

In light of the issues raised by the Secretary, Ms. Borden proposed a fact hearing to gather testimony from available witnesses to address the severity of her injury. Pet'r's Status Rep., filed Jan. 21, 2021. The undersigned issued an order

[2] In his Rule 4 Report, the Secretary describes Ms. Borden's condition as "idiopathic thrombocytopenia purpura" ("ITP"). One of Ms. Borden's physicians similarly concluded her thrombocytopenia purpura was idiopathic. However, Ms. Borden's petition claims she suffered from thrombocytopenia purpura due to a vaccine, meaning it was not idiopathic, according to her.

The Vaccine Injury Table notes that immune thrombocytopenic purpura was formerly called idiopathic thrombocytopenic purpura. These terms would reduce to the same acronym – ITP. To avoid confusion, the full name of the condition will be spelled out.

the following day, noting that testimonial assertions may be insufficient to fulfill the Act's severity requirement. See Order, issued Jan. 22, 2021 (citing Armbruster v. Sec'y of Health & Hum. Servs., No. 17-1856, 2020 WL 3833396, at *11-12 (Fed. Cl. Spec. Mstr. Feb. 5, 2020)). As such, the undersigned explained he was more interested in hearing arguments supporting Ms. Borden's position that she did meet the severity requirement. She was ordered to file a brief addressing precedent about severity and explaining why her case fulfilled the severity requirement.

Ms. Borden filed her brief on February 16, 2021. The Secretary filed his response brief on March 31, 2021, along with attachments to Mosby's Medical Dictionary and Black's Medical Dictionary (exhibits A and B). Ms. Borden filed her reply brief on April 7, 2021.

On June 16, 2021, the undersigned issued an order, explaining he anticipates either finding petitioner satisfies the severity requirement, or finding she has not satisfied the severity requirement and dismissing the case. Nonetheless, the undersigned permitted the parties to explain whether further oral testimony may have been appropriate. See Order, issued June 16, 2021. Ms. Borden filed a status report on June 30, 2021, indicating that she personally wanted to provide witness testimony. A status conference was subsequently scheduled.

During the July 7, 2021 status conference, the parties discussed holding a hearing. Ms. Borden had argued that monitoring her thrombocytopenic purpura constituted a residual effect, and that her bone biopsy constituted a surgical intervention. See Pet'r's Br. at 3-5. The Secretary disagreed with these arguments. During the status conference, the Secretary questioned the value of petitioner's testimony given that the critical issue is a legal question rather than a factual one. The undersigned noted that it was unclear how Ms. Borden's personal testimony would impact her case but stated that testimony from a treating doctor might be informative. See Order, issued July 7, 2021. Accordingly, a hearing was scheduled with the expectation that treating doctors may testify to help resolve the issues. Id.

A pre-hearing status conference was held on July 28, 2021. It was disclosed that Ms. Borden would be the only witness testifying, as no treating doctors were available or willing to testify. Order, issued July 28, 2021.

The fact hearing was held on August 3, 2021. During the subsequent status conference, the undersigned noted other pending cases might determine the outcome of Ms. Borden's case. At the time, the Federal Circuit was deliberating

on Wright v. Sec'y of Health & Hum. Servs., and Leming v. Sec'y of Health & Hum. Servs. had recently been remanded back to the Office of Special Masters from the Court of Federal Claims. Due to these other cases, litigation was temporarily stayed in Ms. Borden's case. See Order, issued Sept. 10, 2021. The Secretary filed a status report on December 6, 2021, providing updates on the Wright and Leming cases.

Petitioner's counsel filed a death certificate for Ms. Borden on March 4, 2022. A status conference was scheduled for April 11, 2022, but then was cancelled. On October 3, 2022, petitioner's counsel filed letters of administration showing Mr. David Borden had been appointed the personal representative of Ms. Borden's estate. The same day, petitioner moved to amend this case's caption, and the caption was amended the following day.

As Leming and Wright appear to have concluded, this case is now ripe for adjudication.

II. Summary of Evidence

Medical records from Kaiser Permanent reflect that Ms. Borden received an influenza vaccine on October 3, 2016. Exhibit 1 at 55; exhibit 10 at 1. Ms. Borden presented to the emergency room approximately six and a half weeks later, on November 18, 2016. Exhibit 3 at 93. Her chief complaint was of a petechial rash, which started about a week prior. Id. Ms. Borden relayed that she was bruising easily and was developing blood blisters. Id. The treaters noted a history of Graves' disease.

During the November 18, 2016 visit, Ms. Borden had blood drawn for further evaluation. Her platelet count was very low, at 3,000/mm^3, whereas normal counts are between 150,000/mm^3 and 450,000/mm^3. Id. at 95, 97. It was noted that she was "severely thrombocytopenic." Id. at 95. The note continues: "[l]ikely this is due to idiopathic thrombocytopenia purpura. . . . Exact cause is unclear." Id. Ms. Borden received IVIG and prednisone, and her platelet counts subsequently improved. She was discharged on November 23, 2016, with instructions to follow-up with her primary care provider for repeat lab work. Id. at 127; exhibit 7 at 13.

Her follow-up visit was on November 28, 2016. Blood work showed her platelet count was dangerously low again. Exhibit 7 at 8, 11-12. The next day, Ms. Borden was evaluated by Dr. Sujatha Nallapareddy, a hematologist. Exhibit 2 at 2. Dr. Nallapareddy recorded that her platelet count dropped to 1,000/mm^3 despite prednisone and IVIG treatment. Id. at 3. He recommended hospitalization

for further treatment. Id. So, Ms. Borden was hospitalized for four days and received a platelet infusion, one round of IVIG and IV-Solumedrol, and a four-day course of oral dexamethasone. Exhibit 3 at 375. A bone marrow biopsy and aspiration were performed on December 2, 2016, to help determine the etiology of Ms. Borden's condition. Id. at 375, 503. An anesthesiologist was present for the biopsy. Id. at 503. The procedures were performed in the Swedish Medical Center minor procedures suite. Exhibit 5 at 8. Surgeons were consulted for a possible splenectomy, but it was determined to not be necessary at that time. Exhibit 3 at 375. The platelet infusion, IVIG, and medications appeared helpful, as her platelet count had risen to 81,000/mm^3 by the time she was discharged on December 3, 2016. Id.

Ms. Borden saw Dr. Nallapareddy for a follow-up visit on December 6, 2016. Exhibit 2 at 4. Her platelet count was 75,000/mm^3. Id. at 5. They discussed a splenectomy versus rituximab and other medications. Id. During a follow-up visit on December 13, 2016, her platelet count was down to 28,000/mm^3. Id. at 8-9. Dr. Nallapareddy interpreted her bone marrow biopsy from the prior week as showing normal bone marrow with enlarged platelets. Id. at 9. Ms. Borden returned to the emergency room on December 23, 2016, and her platelet count was 72,000/mm^3. Exhibit 3 at 764.

On March 6, 2017, roughly five months after receiving the flu vaccination, Ms. Borden was evaluated by Dr. David Schrier, a hematologist and oncologist, for a second opinion regarding treatment of her condition. Exhibit 6 at 35. Dr. Schrier's assessment was that Ms. Borden was doing well, as she had no bleeding or bruising and had been off therapy for a considerable period of time. Id. at 37. Her platelet count was 182,000/mm^3 that day. Id.

Ms. Borden returned to Dr. Schrier's office on November 13, 2017, where she was evaluated by Dr. David Trevarthen.[3] Id. at 29. She reported a rash on her foot for the past month which appeared similar to the petechiae she noticed when she was initially diagnosed with ITP. Id. Dr. Trevarthen advised her that the rash appeared normal and was not consistent with petechiae. Id. at 31. Ms. Borden's platelet count was 195,000/mm^3 at this visit, and she reported no unusual bleeding or any worsening of bruising. Id. at 29, 31. Dr. Trevarthen noted that continuing to periodically monitor her platelet count was reasonable. Id. at 31.

[3] Dr. Schrier had left the practice by this date.

Ms. Borden was admitted to the hospital on June 18, 2018 and was diagnosed with sepsis secondary to a parainfluenza infection. Exhibit 3 at 1037. Her platelet count was 117,000/mm^3. Id. at 1040. She returned to Dr. Trevarthen a few days later, on June 20, 2018. Exhibit 6 at 14. At that visit, her platelet count had recovered to 151,000/mm^3. Id. at 16. Dr. Trevarthen opined her platelet count "may have dipped in the setting of an acute severe illness." Id.

On September 11, 2018, Ms. Borden established a new primary care provider, Barbara Doro. Exhibit 4 at 30. Ms. Doro advised Ms. Borden should get her platelet levels checked every three months. Id. Ms. Borden's platelet count was 192,000/mm^3 on October 10, 2018. Exhibit 6 at 11.

Ms. Borden returned to see Dr. Trevarthen on January 7, 2019. Exhibit 6 at 4. The record notes Ms. Borden had "fairly extensive back surgery done [in] early December." Id. It further notes her platelet count went up to 435,000/mm^3, above the normal range, but Dr. Trevarthen opined this was probably reactive to the surgery. Id. at 4, 6. The record notes her platelet count had returned to normal levels by this visit. Id. at 6. Dr. Trevarthen advised Ms. Borden she should probably continue to monitor her platelet count every 3 months, and then every 6 months if she had a good year. Id.

Given the focus on the severity requirement, the parties did not discuss any medical records after the January 7, 2019 visit. See Pet'r's Br. at 3; Resp't's Br. at 5. Ms. Borden passed away on October 26, 2021. Exhibit 12. The death certificate states she died of acute hypoxic respiratory failure and covid pneumonia. Id.

III. Arguments Advanced in Briefs

The parties were ordered to file briefs addressing whether Ms. Borden had satisfied the severity requirement. See Order, issued Jan. 22, 2021. A summary of the parties' arguments follows.

A. Ms. Borden's Arguments

1. Ms. Borden's bone marrow biopsy constitutes a surgical intervention

Ms. Borden underwent a bone marrow biopsy on December 2, 2016, and she argues that procedure was a surgical intervention as defined by the Act. Pet'r's Br. at 3. In support of her contention, she notes an anesthesiologist was present for the procedure. Id. She argues that the biopsy was a surgery that helped determine the

proper course of treatment for her treatment-resistant ITP, and accordingly, the surgery qualifies as a surgical intervention under the Act. Id. at 3-4.

In support of her position, Ms. Borden cites Ivanchuk v. Sec'y of Health & Hum. Servs., No. 15-357V, 2015 WL 6157016 (Fed. Cl. Spec. Mstr. Sept. 18, 2015) and Leming v. Sec'y of Health & Hum. Servs., No. 18-232V, 2019 WL 5290838.

In her reply brief, Ms. Borden notes that her treating doctors knew she had ITP. Pet'r's Rep. at 1-2. Thus, she argues, the biopsy was not diagnostic but instead performed "to determine the appropriate treatment for a case of ITP refractory to standard treatment." Id. at 2.

2. Ms. Borden's abnormal platelet count satisfies the severity requirement

Ms. Borden concedes that continued monitoring of platelet counts based on a petitioner's own requests and without medical support would not satisfy the severity requirement. However, she argues instead that her abnormal platelet counts were sufficient to show severity. Pet'r's Br. at 4-5.

She distinguishes her case from Deese v. Sec'y of Health & Hum. Servs., No. 19-1127V, 2020 WL 7090213 (Fed. Cl. Spec. Mstr. Nov. 12, 2020). In Deese, the petitioner developed ITP symptoms in early December 2018 and had normal platelet counts by mid-April 2019. Id. at *3. Ms. Borden argues the claim in Deese was dismissed, in part, because the petitioner's request for continued monitoring or petitioner's own worry of possible ITP relapse failed to fulfill the severity requirement. Pet'r's Br. at 4. By contrast, Ms. Borden notes her platelet levels continued to have fluctuations, evincing an ongoing problem. Id. She also notes that her treating physicians advised her to monitor her platelet levels based on those fluctuations. Id. Due to these differences, she argues her case should be allowed to proceed so that experts may offer opinions. Id. at 5.

Next, Ms. Borden argues that continual monitoring of symptoms of an underlying condition satisfies the severity requirement. Id. For support, she cites to Wright v. Sec'y of Health and Hum. Servs., 146 Fed. Cl. 608 (Fed. Cl. 2020). She noted that an appeal had been filed in Wright. The Court of Federal Claims had found that management of conditions satisfies the severity requirement if the testing was conducted due to recurring symptoms. Id. at 612-15. Ms. Borden compares her case to Wright in that her medical providers found continued monitoring of her platelet counts to be a reasonable course. Pet'r's Br. at 5. She

further notes she had abnormal platelets on at least two occasions, validating her treater's recommendations.[4] Id.

In sum, Ms. Borden argues her platelet levels required monitoring due to objective fluctuations, and these facts show her case meets the severity requirement. Pet'r's Rep. at 3-4. Because she had abnormal platelet counts that required monitoring for more than six months, she has satisfied the severity requirement.

B. The Secretary's Arguments

1. Ms. Borden did not suffer direct ITP-related sequelae for six months

At the outset, the Secretary notes that to satisfy the six-month sequelae requirement, Ms. Borden must show residual effects or complications of her ITP through at least April 3, 2017, six months after the vaccine administration date of October 3, 2016. Resp't's Br. at 6. The Secretary argues Ms. Borden's treating hematologist noted she was asymptomatic with normalized platelet count on March 6, 2017, and she required no further treatment after that date. Id. The Secretary further argues Ms. Borden had no further ITP symptoms and required no further treatment for her ITP.

The Secretary acknowledges Ms. Borden had a low platelet count in June 2018 but notes that her physician attributed the decreased platelet count to the sepsis / parainfluenza infection. Id. Furthermore, the Secretary points to the Act's qualifications and aids to interpretation ("QAI"). The QAI defines thrombocytopenic purpura as clinically manifesting petechia, significant bruising, or spontaneous bleeding, *and* by a serum platelet count less than 50,000/mm^3. 42 C.F.R. § 100.3(c)(7) (2020). Although Ms. Borden's platelet count was lower than normal in June of 2018, it was above 50,000/mm^3. Exhibit 3 at 1040.

2. Ms. Borden's bone marrow biopsy was not a surgical intervention

The Secretary observes "surgical intervention" is not defined within the Act. Resp't's Br. at 7; see 42 U.S.C § 300aa–33 (Definitions). Nor has the phrase been defined by the Federal Circuit. The Secretary finds support for his argument that a bone marrow biopsy is not a surgical intervention by referencing the legislative history for the amendment that added the "surgical intervention" prong. Id. at 7-8. The Secretary argues "surgical intervention" was added to the Act in 2000 to allow

[4] In her reply brief, Ms. Borden emphasizes that further monitoring was not due to her anxiety, but rather due to her doctor's concerns. Pet'r's Rep. at 2-3.

for recovery in cases where a vaccinee develops intussusception, which often requires abdominal surgery and typically does not persist for more than six months. Resp't's Br. at 7.

For further support, the Secretary cites several cases that have addressed the Congressional intent and whether purely diagnostic procedures and surgeries are considered "interventions" under the Act. These cases include Spooner v. Sec'y of Health & Hum. Servs., No. 13-159V, 2014 WL 504728, at *5-6 (Fed. Cl. Spec. Mstr. Jan. 16, 2014); Galvin v. Sec'y of Health & Hum. Servs., No. 20-313V, 2020 WL 4593163, at *4 (Fed. Cl. Spec. Mstr. July 6, 2020), aff'd 151 Fed. Cl. 789 (2021); and Stavridis v. Sec'y of Health & Hum. Servs., No. 07-261V, 2009 WL 3837479, at *5 (Fed. Cl. Spec. Mstr. Oct. 29, 2009).

The Secretary also distinguishes the Ivanchuk case, in which the special master held that the bone marrow biopsy in that case was a surgical intervention because the medical records explicitly indicated the procedure was required to institute treatment. 2015 WL 6157016, at *3. The special master carefully noted that the decision "was not a finding that bone marrow biopsy constitutes a surgical intervention in all circumstances." Id.

In sum, the Secretary argues Ms. Borden's bone marrow biopsy and aspiration were diagnostic procedures rather than an intervention to treat a condition. The Secretary analogizes the procedure to the arthrocentesis in Galvin and the lumbar puncture in Spooner. Resp't's Br. at 12.

3. Ms. Borden had normal lab results

The Secretary disputes Ms. Borden's argument that continued monitoring of her platelet count due to abnormal results satisfies the six-month sequelae prong of the severity requirement.[5] Resp't's Br. at 12. For support, the Secretary discusses Crabbe v. Sec'y of Health & Hum. Servs., No. 10-762V, 2011 WL 4436724 (Fed. Cl. Spec. Mstr. Aug. 26, 2011). In Crabbe, the special master ruled that "testing for a possible recurrence [of ITP] is not a 'residual effect' within the meaning of the statute." Id. at *5. In so doing, the special master determined that an increased risk of an injury's recurrence is not sufficient to establish a "residual effect" under the Act; rather, the symptoms need to actually manifest to constitute a residual effect of that injury. Id. at *4-5. The Crabbe rationale was adopted by the special

[5] Additionally, the Secretary notes that the petition was dismissed in Deese due to failure to prosecute and insufficient proof.

master in Wright. No. 16-498V, 2019 WL 1061472, at *11 (Fed. Cl. Spec. Mstr. Jan 18, 2019).[6] The special master in Wright reasoned that blood tests "were done only to test for potential recurrence of [the child's] ITP, not to manage existing symptoms or sequelae thereof." Id.

Next, the Secretary notes that although "residual effects" and "complications" are not defined in the Act, the terms have been interpreted in other cases by using standard medical definitions. Resp't's Br. at 13-14. He cites multiple cases for support, including Parsley v. Sec'y of Health & Hum. Servs., No. 08-781V, 2011 WL 2463539 (Fed. Cl. Spec. Mstr. May 27, 2011). In Parsley, the special master used a medical dictionary to define a "residual effect" as something left behind or resulting from an illness, disability, injury, or condition. Parsley, 2011 WL 2463539, at *16. Thus, the Secretary argues that lab work which reveals normal platelet counts in individuals previously diagnosed with ITP should not be relied on in determining whether a petitioner satisfies the severity requirement. Resp't's Br. at 14. Furthermore, he notes the sequelae clause requires a petitioner to "suffer" and a normal platelet count indicates a lack of suffering. Id. The Secretary also distinguishes the facts of this case from the Court of Federal Claim's ruling in Wright. See Resp't's Br. at 14-15.

IV. Analysis

To prove entitlement under the Act, petitioners must demonstrate their injury is sufficiently severe. This is known as the "severity requirement." Two prongs of the severity requirement are at issue in this case. Petitioners can demonstrate severity by showing the vaccinee "suffered the residual effects or complications" of the vaccine-related injury "for more than 6 months after the administration of the vaccine[.]" 42 U.S.C. § 300aa–11(c)(1)(D)(i). Alternatively, petitioners can show the vaccinee's injury "resulted in inpatient hospitalization and surgical intervention." Id. at § 300aa–11(c)(1)(D)(iii). Such showings must be supported by a preponderance of the evidence, substantiated by medical records or medical opinion. 42 U.S.C. § 300aa–13(a)(1).

The Federal Circuit has interpreted the "residual effects" clause as a limitation of compensation to individuals that are seriously injured by a vaccine. Cloer v. Sec'y of Health & Hum. Servs., 654 F.3d 1322, 1335 (Fed. Cir. 2011), cert. denied, 132 S. Ct. 1908 (2012). Congress added the "surgical intervention"

[6] At the time the Secretary wrote his brief, Wright had been reversed by the Court of Federal Claims, 146 Fed. Cl. 608 (2020), and was on appeal to the Court of Appeals for the Federal Circuit. A decision has since issued, discussed below.

prong in 2000, and the legislative history indicates how to interpret that clause. Proceedings and Debates of the 106th Congress, First Session, 145 Cong. Rec. S15213-03 (November 19, 1999), 1999 WL 34977042.

A. Relevant Precedent

While the parties were developing the evidence and arguments in this case, two cases were being litigated which directly addressed the proper construction of "residual effects" and "surgical intervention." Litigation was stayed in this matter until those cases were resolved. Below is a summary of those cases.

1. Leming v. Secretary of Health and Human Services

In Leming, the special master initially found the petitioners' daughter, A.L., was entitled to compensation because she suffered from immune thrombocytopenic purpura within weeks of receiving a measles-mumps-rubella-varicella vaccine. The special master found that the injury resulted in hospitalization and a "surgical intervention," thus satisfying the severity requirement. Leming v. Sec'y of Health & Hum. Servs., No. 18-232V, 2019 WL 5290838 (Fed. Cl. Spec. Mstr. July 12, 2019). The Secretary filed a motion for review and argued the special master improperly interpreted "surgical intervention" within the context of the Act and the legislative history. On review, the Court of Federal Claims disagreed with the special master's analysis that A.L.'s bone marrow biopsy was a surgical intervention performed "to institute treatment rather than diagnose" and remanded the case in light of the finding that A.L. did not undergo a surgical intervention. Leming, 154 Fed. Cl. 325, 334-35 (June 16, 2021) ("Leming I").

On remand, the special master found that A.L.'s injury did not satisfy the severity requirement and dismissed the claim. 2022 WL 3371016 (Fed. Cl. Spec. Mstr. Jan. 26, 2022). The petitioners' motion for reconsideration was denied. 2022 WL 3444742. The Court of Federal Claims then denied the petitioners' second motion for review. --- Fed. Cl. ---, 2022 WL 3723131 (2022) ("Leming II"). The arguments raised by petitioners in Leming II included claiming the special master was arbitrary and capricious for determining (1) the presence of giant platelets was not a residual effect of ITP and (2) that the child was not restricted from receiving immunizations until her sixth birthday. Id. at *11-16.

2. Wright v. Secretary of Health and Human Services

A similar issue arose in the Wright case. In Wright, the petitioner alleged her son, B.W., developed immune thrombocytopenic purpura after receiving a measles-mumps-rubella vaccine. No. 16-498V, 2019 WL 1061472 (Fed. Cl. Spec.

Mstr. Jan. 18, 2019). A few months later, B.W.'s blood tests indicated a normal platelet count, and B.W.'s pediatrician opined the condition had resolved. Id. at *2. More than six months after the vaccination, B.W. returned to his pediatrician multiple times due to bruising; however, blood tests from those visits revealed platelet counts well about 50,000/mm^3 and within normal limits. Id. at *2-3. Holding that testing for a possible recurrence of ITP was not a residual effect within the meaning of the Act, the special master dismissed the petition for failure to satisfy the severity requirement. Id. at *11-13.

Ms. Wright filed a motion for review. The Court of Federal Claims ruled that the special master erred as a matter of law, reasoning that "ordering platelet counts when a patient with a history of ITP is presented with bruising" was "within the doctor's reasonable standard of care" and that the testing was "causally connected to the vaccine injury[.]" 146 Fed. Cl. 608, 614-15 (2019). In essence, the Court of Federal Claims found that testing for a condition should be compensated if the testing is connected to an underlying vaccine injury and the testing is prompted by subsequent symptoms of the injury. After the case was remanded and damages were awarded, the Secretary appealed.

On appeal, the Court of Appeals for the Federal Circuit reversed. It held that relatively non-invasive monitoring was not a "residual effect" under the severity requirement. 22 F.4th 999, 1005-06 (Fed. Cir. 2022). The Court also held that bruising, after blood tests indicated that ITP had resolved, was not a "residual effect" under the severity requirement. Id. at 1005.

B. Ms. Borden has not satisfied the severity requirement

For the reasons explained below, Ms. Borden has not demonstrated her injury was sufficiently severe to justify entitlement under the Act.

Ms. Borden received an influenza vaccine on October 3, 2016. Exhibit 1 at 55. To demonstrate she suffered the residual effects of an injury from that vaccine for more than 6 months, Ms. Borden would need to show residual effects through at least April 3, 2017, or that she underwent a surgical intervention.

About six and a half weeks after the vaccine, Ms. Borden arrived at an emergency room with a petechial rash, which started about a week prior. Exhibit 3 at 93. She was bruising easily and was developing blood blisters. Id. Her platelet count was extremely low, at 3,000/mm^3, well below normal limits. Id. at 95, 97. The treating physician opined she suffered from idiopathic thrombocytopenia purpura. Id. at 95.

On November 28, 2016, Ms. Borden's platelet court was concerning low once again. Exhibit 7 at 8, 11-12. Per recommendation by Dr. Nallapareddy she was hospitalized and received a platelet infusion and other treatment protocols. Exhibit 3 at 375.

A few days later, on December 2, 2016, a bone marrow biopsy and a bone marrow aspiration were performed on Ms. Borden. Id. at 375, 503. The parties dispute whether these procedures constitute a "surgical intervention." As discussed below in Section IV.B.1, these procedures are not surgical interventions within the meaning of the Act.

Ms. Borden's platelet count was 81,000/mm^3 when she was discharged on December 3, 2016. Id. at 375. On December 6, 2016, Ms. Borden's platelet count was 75,000/mm^3. Exhibit 2 at 5. Soon after, on December 13, 2016, her platelet count fell to 28,000/mm^3. Id. at 8-9. Dr. Nallapareddy interpreted her bone marrow biopsy from the prior week as showing normal bone marrow with enlarged platelets. Id. at 9. Ms. Borden had a platelet count of 72,000/mm^3 when she returned to the ER on December 23, 2016. Exhibit 3 at 764.

Dr. Schrier assessed that Ms. Borden was doing well on March 6, 2017, as she had no recent bleeding or bruising, and her platelet count was 182,000/mm^3 that day. Exhibit 6 at 35-37. This test, approximately five months after her flu vaccine, suggests that her condition had resolved. This finding is bolstered by the lack of visits to doctors or emergency rooms for the next several months.

On November 13, 2017, Ms. Borden returned to Dr. Schrier's office, and was evaluated by Dr. David Trevarthen. Id. at 29. Though she was concerned about a rash that appeared similar to a petechiae, Dr. Trevarthen advised her that the rash appeared normal. Id. at 31. Ms. Borden's platelet count was normal at this visit, at 195,000/mm^3. Id. at 29, 31. There are no additional medical records recording a platelet count of below 100,000/mm^3, let alone below 50,000/mm^3.[7]

1. Ms. Borden's bone marrow biopsy and aspiration were not surgical interventions

In Leming I, the Court of Federal Claims held that A.L.'s bone marrow biopsy and aspiration were not "surgical intervention[s]." 154 Fed. Cl. at 333-35. The Court in Leming I determined that the bone marrow biopsy and aspiration performed on A.L. qualified as surgical *procedures*, but also ruled that the bone

[7] See 42 C.F.R. § 100.3(c)(7) (2020) (requiring a platelet count of less than 50,000/mm^3 to evince thrombocytopenic purpura).

marrow aspiration and biopsy could not be characterized as surgical *interventions* under the Act. Id. at 332-33. This distinction was reached in part due to dictionary definitions; the Court recognized than an "intervention" is intended to or does in fact alter the course of a disease. Id. at 333. As such, the Court found "the term 'surgical intervention' is best read to include only those surgical procedures that are administered to directly treat a condition once it has been diagnosed." Id. at 333. Thus, purely diagnostic surgical procedures are not interventions.

For support, the Court of Federal Claims cites to and interprets the legislative history of the 2000 amendment, which birthed the "surgical interventions" clause. Id. at 333-34; see 1999 WL 34977042. In essence, the clause was added to address cases in which individuals developed intussusception after receiving a rotavirus vaccine. That condition, when properly treated, would not result in 6 months of injury or death, hence the justification to modify the Act to provide compensation for that vaccine-induced injury.

The undersigned finds the reasoning in Leming I to be persuasive. When Congress added the "surgical intervention" language, it was not intended to mitigate the Act's severity requirement such that any surgical intervention would become equivalent to six months of residual effects or sequela. The legislative history states:

> To our knowledge, the amendment would only apply to circumstances under which a vaccine recipient suffered from intussusception as a result of administration of the rotavirus vaccine. The amendment is not intended to expand jurisdiction to other vaccines listed in the Program's Vaccine Injury Table.

1999 WL 34977042.

The bone marrow biopsy and aspiration Ms. Borden received on December 2, 2016 were not "surgical interventions." The procedures, even if considered surgeries, were performed to help determine the etiology of Ms. Borden's condition rather than provide treatment. This is quite different from the splenectomy that was considered by the surgeons. Furthermore, the legislative history makes clear that "surgical intervention" was intended to have a limited application. As such, the procedures Ms. Borden received, even if considered surgeries, do not satisfy the "surgical intervention" prong of the severity requirement.

2. Ms. Borden's abnormal platelet counts do not satisfy the severity requirement

Ms. Borden attempts to argue she had abnormal platelet counts more than six months after her vaccine, and that the abnormal results and need for monitoring demonstrate she satisfied the severity requirement. For the reasons noted below, this argument is not persuasive.

Ms. Borden received the flu vaccine on October 3, 2016. She became thrombocytopenic and had dangerously low platelet counts. However, about five months later, in March of 2017, Ms. Borden's platelet levels had returned to a normal count of 182,000/mm^3. Her platelet levels thereafter never fell to dangerously low levels.

The next time she went to a hospital was about eight months later, in November of 2017, and her platelet count was 195,000/mm^3 at that visit. In June of 2018, Ms. Borden's platelet count fell below 150,000/mm^3, down to 117,000/mm^3. Arguably, this was abnormal count. However, her treating doctors felt that this was due to a parainfluenza infection and/or sepsis. Furthermore, this platelet count does not evince thrombocytopenia purpura, as defined in the Vaccine Table, because it is not less than 50,000/mm^3.

Ms. Borden also had an abnormally high platelet count of 435,000/mm^3 after a back surgery, which her physician thought was caused by the surgery. But, an elevated platelet count is precisely the opposite of thrombocytopenia.

Based on these objective tests, it seems more likely that Ms. Borden had an acute form of thrombocytopenia rather than a relapsing or chronic version of the disease. Her blood work strongly suggests her condition resolved within six months. Although it may have been reasonable for Ms. Borden to continue to get blood tests, the risk of a recurrence of an injury without an actual recurrence is not a residual effect within the meaning of the Act. Crabbe, 2011 WL 4436724, at *5. Furthermore, relatively non-invasive monitoring is not a "residual effect" under the Act. Wright, 22 F.4th at 1005-06.

V. Conclusion

Ms. Borden has not demonstrated that her condition has satisfied the severity requirement. Without such a showing, she cannot establish entitlement to compensation. Accordingly, the Clerk's Office is instructed to enter judgment in accordance with this decision unless a motion for review is filed. Information

about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master